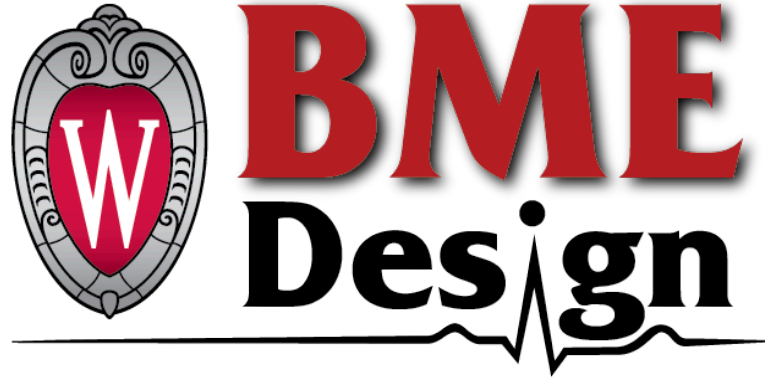




Pediatric Kidney Transplant Surgical Instrument Development

BME 200/300 Engineering Design (Section 309)

Preliminary Report

Date of Last Revision: 10/06/2026

Client(s): Dr. Kelly Collins, M.D. and Dr. Jennifer Phillips, M.D.

Advisor: Professor Shawn Gomez

Team Members

Co-Leader: Noa Biener (nbiener@wisc.edu)

Co-Leader: Ishita Bhardwa (ibhardwaj3@wisc.edu)

Communicator: Mariamawit Tefera(mstefera@wisc.edu)

BWIG: Madison Poza (mpoza@wisc.edu)

BSAC: Lily Walden (lwalden@wisc.edu)

BPAG: Brannick Larson (bllarson8@wisc.edu)

Abstract

Kidney failure is a prevalent medical issue that affects about 830,000 people in the United States. Approximately 5600 of these people are under the age of 18. Kidney transplant is the preferred method of treatment for kidney failure. The majority of kidneys that are transplanted are adult kidneys, even when the patients are pediatric. Currently, the majority of surgical instruments used in the transplant procedure are designed for adult patients which results in difficulties in surgeries on children. A vascular clamp is being designed specifically for pediatric patients who are receiving this procedure. The instrument will feature a detachable jaw and multiple jaws will be manufactured with varying curvatures for the varying sizes of the pediatric patients. Testing will be needed to be done to ensure the jaw does not detach in the middle of surgery and that excessive occlusive force is not applied to delicate blood vessels. This will result in ease of surgery and will remove many of the technical difficulties associated with using adult sized vascular clamps while operating on pediatric patients.

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Introduction

Kidney transplantation is the preferred treatment for children and adolescents with stage 5 chronic kidney disease and provides improved long-term outcomes compared with remaining on dialysis [1]. In the United States, kidney transplantation is the most common form of renal replacement therapy among children living with end-stage renal disease (ESRD), with approximately 72% of prevalent pediatric patients having a functioning transplant in 2016 [2]. However, kidney transplantation in small children is technically demanding because of their smaller anatomy, limited surgical space, and increased risk of vascular complications. Recipients weighing 15 kg or less are considered a particularly challenging group because their size can make vascular access and anastomosis more difficult and increase the risk of complications that may lead to graft loss [3]. Children under 20 kg may also have anomalous vascular anatomy that further complicates transplantation [4]. During transplantation, vascular clamps are used to temporarily control blood flow while the donor and recipient vessels are connected [5]. However, the mechanical force required to occlude a vessel can also cause vascular injury. Studies investigating vascular clamps have demonstrated that clamp type, pressure, and applied force can influence endothelial damage [6,7]. Babin-Ebell et al. found that endothelial damage occurred during aortic cross-clamping and that low-force clamping helped preserve the integrity of the vessel wall [8]. Although these studies were not performed specifically on pediatric renal vessels, they demonstrate the importance of controlling clamping force, particularly when working with smaller and more delicate vessels. Several competing pediatric clamp designs are currently available. Cooley/DeBakey-style pediatric clamps use atraumatic serrations or teeth and a ratcheting mechanism to maintain vessel occlusion, but their handles can be bulky and obtrusive within a shallow surgical field [5]. Baby renal clamps use modified handle angles and very small jaws to improve access to smaller vessels, but their specialized dimensions may limit their use across different pediatric age and weight groups [6]. Pediatric bulldog clamps use a compact, spring-loaded occlusion mechanism without traditional handles, but are designed for specific vessel sizes and therefore may have limited adaptability to varying pediatric anatomy [9]. Patents have also explored methods of controlling vascular clamping force, including variable-force microvascular clamps and atraumatic balloon clamps that distribute pressure around the vessel [10,11]. These existing designs demonstrate that clamp size, jaw geometry, and closing force are important factors in achieving reliable vessel occlusion while minimizing tissue damage. However, there remains a need for a vascular clamp specifically optimized for pediatric kidney transplantation that can accommodate small vessels and the shallow surgical field of a child while applying a controlled force sufficient for reliable occlusion without unnecessary vascular injury. The goal of this project is therefore to address the limitations of existing designs by investigating a pediatric vascular clamp that balances appropriate size, vessel accessibility, and controlled clamping force.

Background

End-stage renal disease (ESRD) is kidney failure that requires a replacement. Kidney transplantation is the preferred treatment for children with ESRD but the procedure can be more challenging than adult transplantation because children have smaller blood vessels and a smaller abdominal cavity. These differences increase the need for appropriately sized surgical instruments with careful control of vascular clamping force to reduce the risk of damage or other complications [12, 13, 14]. Vascular clamps are used during transplantation to temporarily block the flow of blood while the surgeon attaches the vessels and kidney. Existing pediatric clamps include the Cooley/DeBakey, baby renal, and bulldog designs. The Cooley/DeBakey clamps use atraumatic jaws and a ratchet system but the handles and overall size is too bulky [15]. Baby renal clamps have smaller jaws and modified handles but are mainly used for very young pediatric patients [16]. Bulldog clamps eliminate the bulky handles with a spring mechanism but are designed for a specific blood vessel size [17]. These existing designs show that there is a need for a clamp that can accommodate a wider range of pediatric vessel sizes, fitting in the children's surgical area, and can maintain a controlled clamping force. The goal of this project is to develop a scaled vascular clamp with adjustable jaw sizes and reduced or controlled clamping force for pediatric patients. This design is intended to provide consistent and controlled force while reducing the space needed and the risk of damaging pediatric blood vessels.

Client Information

The clients are UW Health pediatric transplant surgeons, Dr. Kelly Collins and Dr. Jennifer Phillips, who identified a need for improved vascular clamping instrumentation for pediatric kidney transplantation.

Design Specifications

The clamp should accommodate different pediatric vessel sizes, use atraumatic jaws to avoid excessive damage, and provide an adjustable clamping force of 2–5 N. It should also be compact, sterilizable, biocompatible, latex-free, reusable, and manufacturable [Appendix A].

Preliminary Designs

Force Mechanism Designs

Force Design 1: Ratchet System

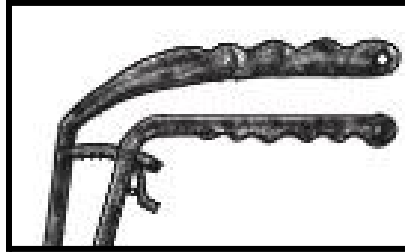


Figure 1: Ratchet system

The first proposed force mechanism design is the ratchet system. This design is created by manufacturing a gear-like structure between both jaws and one jaw can incrementally adjust by sliding through the ridges. An additional relief lever can be created to more efficiently lock and release the jaw as needed. This design is advantageous due to its ability to maintain force without continuous pressure by the user. Disadvantages for this design may include larger force jumps between each notch position, no tactile feedback by the user regarding how much pressure is being applied, and the requirement of more mechanical components, such as the relief lever.

Force Design 2: Spring Mechanism

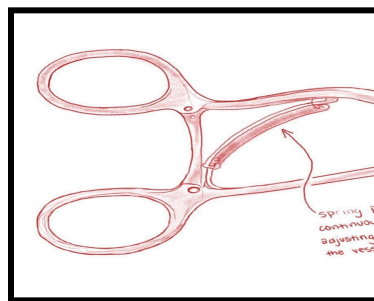


Figure 2: Spring Mechanism

The second proposed force mechanism is the spring mechanism. This design utilizes a spring to help control the applied force to the patient's vessel. The spring would be placed between both jaws, most likely closer to the finger handles to maximize tactile feedback by the user. This reduces the likelihood of the surgeon applying too much force to damage the vessel. Potential

concerns for this design include hand exhaustion for the surgeon as they apply continuous pressure, spring fatigue over time as it is continuously used, and the spring also requires fine adjustments and tuning every so often to get the spring force at the correct level of force.

Force Design 3: Adjustable Dial Mechanism

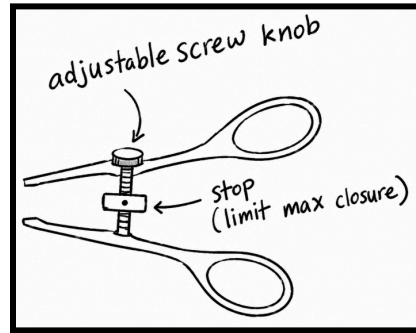


Figure 3: Adjustable Dial Mechanism

The third and final proposed force mechanism is the adjustable dial mechanism. This design utilizes a nut and bolt combination to adjust the force, where the bolt/screw is incorporated into the clamp to present the maximum force possible in the design, while the nut is applied through threads present above the handles to allow for lowering of the forces as it is continuously screwed. This design has the advantage of providing a wide range of force settings while also allowing the force to be adjusted more precisely through smaller turns of the nut. Some disadvantages this design may have is longer adjustment time due to the screwing needed and threads could wear over time as the nut is continuously adjusted.

Detachable Jaw Designs

Detachable Jaws Design 1: Screw-In Mechanism

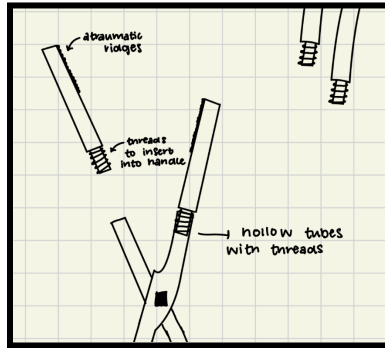


Figure 4: Screw-In mechanism

The first proposed design is the screw-in mechanism. It uses threads and a screw mechanism to securely attach jaws. Threads will be added to the outside of the jaw as well as to a hollow cylindrical portion of the end of the clamp. The two components will then be screwed together and can be unscrewed later if a different size is desired. The advantages of this design are its ease of use and fabrication. This design is very easy for the surgeon to understand and use as well to change in the middle of the procedure if a different curvature of the jaw is desired. The disadvantages of this design are that the threads may wear down eventually due to friction which may result in a loss in stability. Further, insecure attachment is easy to do in a hurry but can result in the jaw detaching from the clamp mid-surgery and falling into the surgical field.

Detachable Jaws Design 2: Pop-In Mechanism

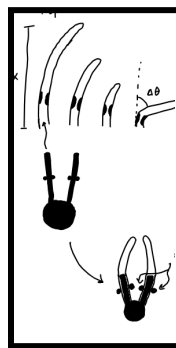


Figure 5: Pop-In mechanism

The second proposed design is the pop-in mechanism. It allows for quick attachment of different jaws using a mechanism similar to that of a backpack buckle. A circular protrusion of some width is created on the clamp. The jaw's end is hollowed out and also has a similar protrusion on

the inside. The clamp is pushed into the jaw and the protrusions lock into each other which allows the jaw to be attached to the clamp. The advantages of this design include its low time required to connect the jaw to the clamp. The disadvantages of this design are that it has a long fabrication process, metal has a low flexibility if made too thick which could cause the jaw to bend which would result in a loss of stability or it could cause the jaw to snap, rendering the instrument useless.

Detachable Jaws Design 3: Sliding Mechanism

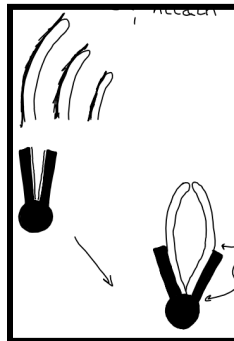


Figure 6: Sliding Mechanism

The final proposed design for detachable jaws is the sliding mechanism. This mechanism is constructed by creating ridges along the high end component of the jaw and grooves within the lower end of the jaw. This allows for the jaw ends to slide into the lower component until it fits in tightly. An additional locking mechanism may be added to ensure further stability. This design is particularly advantageous due to how easy it is for the client to use. One disadvantage for this design is the possible incorporation of an additional securement/attachment mechanism that should help to prevent any accidental removal of the jaws.

Preliminary Design Evaluation

Two weighted design matrices were developed to evaluate some proposed mechanisms for force modification and adjustment, to prevent extensive occlusion, and for detachment and adjustment of clamp jaws, in order to accommodate a large range of vessel sizes. Each design was scored using a five-point scale based on criteria weighted according to their importance to the device's efficiency, performance and usability.

Design Evaluation For Force Adjustment Mechanisms

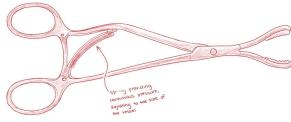
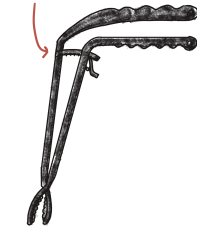
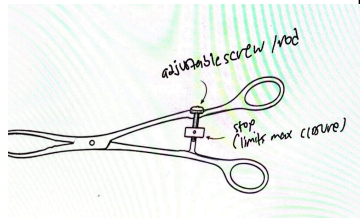
Design Criteria	Spring Mechanism		Ratchet System		Adjustable Screw/Dial Mechanism	
						
Safety (30)	4/5	24	5/5	30	5/5	30
Versatility (25)	4/5	20	4/5	20	4/5	20
Ease of Use (20)	3/5	12	5/5	20	4/5	16
Ease of Fabrication (15)	4/5	12	5/5	15	3/5	9
Cost (10)	5/5	10	5/5	10	5/5	10
Total Score (100)	78		95		85	

Table 1: Design matrix used to evaluate force adjustment mechanisms

Reasonings For Force Mechanism Design Scores

Safety (30)

Safety considers the security of the design, including how well and how consistently it can maintain the level of force expected for anastomosis without causing irreparable damage to the patient's blood vessels. The spring was ranked lowest because constant pressure has to be provided to supply the correct amount of force, unless a locking mechanism is added, in which case rupturing or blood vessels damage can occur if the surgeon supplies too much pressure and locks the instrument at that level of force. The ratchet system was ranked highest because once the ratchet is adjusted to the correct setting, there will be a constant supply of pressure on the vessels and the surgeon can slowly continue to supply force until the appropriate amount is reached. The adjustable screw was also given a high ranking because it can be slowly adjusted and once set, it will supply a consistent amount of force on the vessel. The chance of damaging vessels is low because to tighten the grip, the screw must be adjusted first.

Versatility (25)

Versatility considers the instrument's ability to adjust the force, including aspects such as how easy it is to adjust the force setting through the mechanism and how many different force settings are present to accommodate for patients with different sized vessels. The spring allows the clamping force to change as the spring is compressed, but it does not provide as many ways to precisely adjust the force. The amount of force is mainly dependent on the spring's stiffness and compression, so changing to a different force would likely require changing the spring or its setup. The ratchet system provides multiple fixed positions that can change the amount of clamping force. The surgeon can move the clamp to different ratchet positions depending on the vessel and desired force, while the ratchet keeps the clamp in place. The adjustment screw/dial mechanism's force can be changed by turning the screw or dial. Unlike the ratchet, which has specific positions, the screw can allow more gradual adjustment to the clamping force.

Ease Of Fabrication (15)

The ease of fabrication, focuses on the difficulty to construct the design. Each design was ranked based on the added components, complexity of the mechanism, and how easily the parts could be manufactured and assembled. The ratchet design received the highest score because the mechanism for controlling the force does not have to be adjusted and tested for perfecting the force distribution. There is one added part which is the lever for the ratchet which is held onto the main piece by a spring. This design is the easiest to test since perfecting the force is not required here. The spring mechanism is slightly easier to manufacture but will require a lot of testing and adjusting to get the force balance to where we want it. The adjustable screw received

the lowest score because it will take longer to figure out a screw system that can curve. As the two sections tighten, the overlap will shift because they spin around a center point. So, the screw will have to be able to twist or spin and testing and manufacturing could be difficult.

Ease Of Use (20)

The ease of use of the design focuses on ergonomics, such as comfortability for the surgeon when holding and using the instrument or efficiency and speed in modifying the force during procedures. This criteria was given medium importance because while it is important to consider how easily potential clients should be able to alter the amount of force during surgery, it may be more difficult to consider this aspect during the fabrication process due to the complexity of existent force mechanisms. The spring system design received the lowest score in this category because the mechanism requires the user to push against the spring to adjust the force as needed. This can be time consuming and tedious for the surgeon as well as extend the length of the surgery, exposing the patient to additional health risks. The ratchet system received the highest score in this category because modification of the force can be done through simple movements and adjustments of the relief lever. There also is no need for additional applied force by the user and not much extra time needed to re-secure the mechanism. The adjustable dial design received a medium score in ease of use because while it may not require additional force or pressure, screwing and readjusting the dial when the amount of force needs to be changed during surgery may still increase the surgical time span and exhaust the surgeon.

Cost (10)

The cost of the design reflects both the raw material price and the overall affordability of manufacturing. For the cost criterion, all three designs received full points in the matrix. The spring mechanism uses the same general material as the other concepts, so its material cost should be comparable. Any difference in cost would mainly come from the amount of material needed or the dimensions of the components. The ratchet system also received the highest score. Although its geometry may be somewhat more complex, this does not necessarily make the material significantly more expensive. This design received full points for the same reason. It has a similar amount of material as well as the number of components. It is also similar in the amount of equipment required to make it.

Overall, the ratchet system received the highest score of (95/100), followed by the adjustable screw/dial mechanism (85/100) and spring mechanism (78/100). The ratchet system was preferred because it provides incremental force adjustments, maintains its position without continuous pressure from the surgeon, and allows for relatively simple fabrication and operation.

Design Evaluation For Detachable Jaw Mechanisms

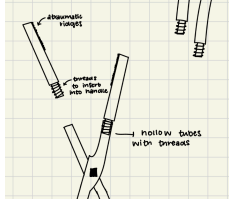
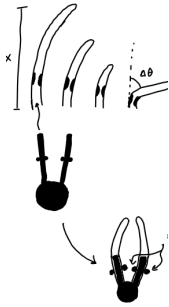
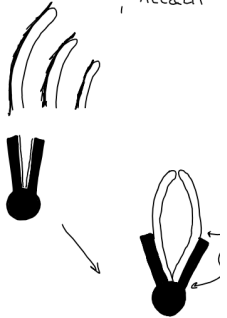
Design Criteria	Screw Mechanism		Pop-In Screw/Swiffer Mop Extension Mechanism		Sliding Mechanism	
						
Stability (30)	5/5	30	4/5	24	3/5	18
Ease of Use (25)	3/5	15	4/5	20	5/5	25
Ease of Fabrication (20)	5/5	20	3/5	12	4/5	16
Versatility (15)	3/5	9	5/5	15	4/5	12
Cost (10)	5/5	10	4/5	8	3/5	6
Total Score (100)	84		79		77	

Table 2: Design matrix used to evaluate jaw attachment mechanisms

Reasoning For Jaw Attachment Mechanism Scores

Stability (30)

The stability criteria focuses on how stable and secure the detachable end/jaw is and whether it will come out if too much force is used——. The screw mechanism was ranked highest due to its a threaded connection, creating a positive mechanical lock between the two halves; the threads have to be unscrewed for the joint to separate, so it cannot be pulled apart by axial force alone. Even under heavy loading during use, the mating threads keep the detachable end firmly sealed, making this the most secure connection of the three. The mechanism's pop-in connection relies on a spring-loaded tab or detent snapping into a groove rather than a full threaded engagement. This holds the pieces together securely under normal use, but because the retention depends on a

small tab rather than continuous threads, there is a slightly higher chance the connection could release if enough force or the wrong angle of pull is applied or after wear and tear. The sliding mechanism scored lower because it relies on a friction fit or a simple sliding channel to hold the jaw in place, with no threaded or positive mechanical lock. This makes it the easiest to attach/detach, but also the least resistant to being pulled apart; if too much force is applied along the sliding axis, the detachable end is more likely to slip or come loose compared to the screw or pop-in designs.

Ease Of Use (25)

The ease of use of the design focuses again on ergonomics, particularly considering the ease, efficiency, and speed of removing and changing detachable ends during procedures. This criteria was given a higher ranking because the absence or inefficiency to adjust or change the clamps' ends is one of the main issues with current market designs and is one of the larger focuses of the project requested by the client. The screw mechanism received the lowest score in ease of use because detaching the ends from the jaw requires immense torsional force by the surgeon and can take a long amount of time to completely remove and reattach ends. This can be time consuming and tedious for the surgeon as well as extend the length of the surgery, exposing the patient to additional health risks. The pop-in screw design received a medium score in ease of use because detachment from jaws only requires a simple push from the thumb and index finger of the user, but the mechanism may get stuck or be very difficult to remove if precise force is not applied at the correct location on the ends. The sliding mechanism received the highest score in this category because the detachment mechanism is very simple to use and requires little to no additional force or movement by the surgeon. While this mechanism may be very easy to adjust and manipulate, it may be less secure than other designs.

Ease Of Fabrication (20)

For ease of fabrication, the designs were ranked based on the number of components, complexity of the mechanism, and how easily the parts could be manufactured and assembled. The screw design received the highest score because it has a relatively simple construction with fewer complicated components. The screw and jaw components can be fabricated separately and assembled without requiring many intricate features, making the design straightforward to manufacture. We would worry less about the pieces properly fitting with each other. The pop-in mechanism received a lower score because it involves multiple components that need to fit together properly. The pop-in connection and screw-based attachment would require more precise dimensions to ensure that the pieces connect. The sliding mechanism has a score between the other two designs. While the basic structure is relatively simple, the sliding components need to be fabricated with appropriate tolerances so that they can move smoothly while maintaining a secure connection. This adds some fabrication difficulty compared with the screw mechanism.

Versatility (15)

Versatility is the ability of the design to accommodate multiple different sized and potentially different shaped jaws. For this criteria, the most versatile designs have the highest scores i.e. they can better accommodate differently shaped jaws. The screw mechanism received full points because the threads allow for any jaw to be screwed in as long as it has an end that is similar in shape and size and can fit within the clamp. The pop-in screw received a slightly lower score as it requires holes in the side of the jaw to fit a button on the clamp. The surgeon requires that the clamp not shake or rattle while it is in use. If too short of a distance is used while making the holes to attach the jaw to the clamp, the jaw will rattle. This limits the use of short lengths of jaws since there will not be enough space on the jaw to accommodate both the requirements. The sliding mechanism received the lowest score because it cannot safely accommodate jaws that are too long. There is a risk of shaking, rattling, falling out, or shifting in position when the jaws are attached to the clamp. If the jaw is too long, the entire instrument is destabilized and hence they cannot be used.

Cost (10)

The cost of the design reflects both the raw material price and the overall affordability of manufacturing. All three designs use approximately equal amounts of material and so this section mostly talks about the affordability of manufacturing. The screw mechanism received full points because the threads are easy to add to the jaws and the clamp. The procedure is simple and not much equipment or time is required for this design. The pop-in screw received a slightly lower score because the button required to pop-in and pop-out will add an additional material cost. It also requires more complicated equipment to make which will add an additional surcharge. The sliding mechanism received the lowest score as it only requires one material due to which there is no additional material cost. However, this design has a complicated shape. It requires a slide on both the clamp and the jaw. This increases the amount of metal required for manufacturing. Since there is also a high chance of error in the manufacturing process due to the degree of certainty required, it is anticipated that this design will have the maximum amount of wasted material. These factors cause it to be the most expensive design.

The screw-in mechanism received the highest score of 84/100, followed by the pop-in mechanism (79/100) and sliding mechanism (77/100). The screw-in mechanism was favored for its secure threaded connection, straightforward fabrication, and lower anticipated manufacturing cost. Although it requires more time to exchange jaws, its stability was considered more important for maintaining a reliable connection during surgery.

Proposed final design

Based on the weighted design matrices and the team's preliminary design evaluation, the proposed final design combines a ratchet-based force adjustment system with interchangeable screw-in jaws. The ratchet mechanism will allow surgeons to incrementally adjust and maintain clamping pressure without continuously applying force. A release lever will allow the mechanism to be disengaged when necessary. The screw-in attachment system will use matching threaded connections between the clamp and detachable jaws, allowing different jaw sizes to be securely attached to accommodate varying vessel dimensions.

The proposed design aims to provide reliable vessel occlusion while minimizing excessive compression and improving adaptability to pediatric kidney transplant procedures. The clamp will maintain appropriate jaw dimensions for adult donor vessels while reducing its overall working depth to accommodate the smaller pediatric surgical field.

Fabrication

Initial Prototype Fabrication

To test the efficiency of the proposed mechanisms, an initial prototype of the proposed clamp design will be fabricated through Fused Deposition Modeling (FDM) 3D printing. The selected printing material will be polylactic acid (PLA), as it has very high rigidity (allowing it to simulate the more rigid structure of metal materials), provides rapid printing (many prototypes can be constructed consecutively as small adjustments are made from the intended design), and is cheaper and more accessible than other printing material options (This is the main material used in the 3D printers available at Wendt Commons).

The clamp design will be constructed from a digital 3D model generated through a CAD modeling software, such as SolidWorks. The model will be exported as an assembly of previously segmented components, including symmetric arms with a connection hinge, finger rings and a ratchet system, and detachable jaws. An assembly of separate pieces is preferred to a single structure as this can avoid any fusing (and therefore blocking) of moving joints. Once the print has been processed, supports will be removed, sanding will happen to straighten surfaces, and any additional modifications will be done to finalize the printed prototype. Additionally, any movable mechanisms will be exercised for smoothness, ease of use, and amount of force needed to operate the movement.

To produce the most accurate and representative model that also accentuates the key mechanical features of the design, SolidWorks' geometrical tools will be used. The ratchet system (incremental locking mechanism) attached to the finger ring handles will be generated by

constructing a sloped, staggered, gear-like design (that allows for the handle to easily slide past each level of force until it reaches the targeted force, where it can lock with an additional lever). This can be created using tools such as the Sketched Arc and Linear Pattern commands (to produce several adjacent copies of the staggered structure) and Boss-Extrude features (to create the design in 3D). For interchangeable, patient-specific sized jaws, the internal socket connection in the lower arm of the jaws will have coarse threads, which can be generated with the Thread tool. Finally, any serrations added in for securement to vessels will be cut into the jaws' faces using a combination of the Cut-Extrude (creating grooves in the design) and Linear Pattern (which will replicate the ridges along a longer length).

Final Prototype Fabrication

Once a printed prototype has been designed and tested for mechanism efficiency, a final design can be manufactured for clinical long-term use. The design should be composed of 400 series stainless steel (or more specifically, grades such as AISI 410 or 420) as these are the most common material types used for clinical grade vascular clamps due to their high corrosion resistance, high strength, hardness, and heat-clavable qualities [18]. If stainless steel is not available for use, titanium is an alternative option because of its high biocompatibility and its lightweightedness, minimizing fatigue for the surgeon and maximizing comfortability during longer surgeries [18]. The selected material can be bought either in bulk where the metal piece can then undergo a forging process (heating and pressing it into the proper shape) (a process helps to increase durability and mechanical strength, making it critical to the function of the instrument) or the metal piece can be purchased already shaped with the intended structure of the clamp or at the very least, its bare skeletal structure [18].

After the material has been obtained and constructed into the proper shape, additional methods allow for the necessary adjustments to be incorporated. Processes such as CNC and lathe machining, VMC systems, and precision grinders can help to produce features including; several predetermined sized jaws (to accommodate patient vessel sizes requested by the client), serrations (to help with gently yet securely applying force to the vessels), ratchets (to allow for incremental adjustment of the force of occlusion), and hinges or fine surgical tips (to more precisely reach and occlude the target vessels for occlusion) [18]. Additionally, fine tuning processes, such as CNC sharpening or surface grinding, can produce sharper and more precise edges, better jaw alignment, and smoother connection and articulation between all parts [18].

Other heat treatment procedures can be additionally conducted to help with elevating certain advantageous properties of the material. Hardening, where the metal is heated and rapidly cooled, can help to increase hardness of the material [18]. Tempering, where the metal is reheated below critical temperature and cooled with air temperature, helps with reducing brittleness while maintaining the same strength [18]. Annealing, where material is raised about recrystallization temperature and is later cooled at a controlled rate, can help to increase ductility and flexibility while also relieving any internal stresses present [18].

Finally, the clamp design can go through several protective measures to ensure long term life in service as well as minimize instrument damage and cytotoxicity. Passivation, which is done by placing the material in an acidic solution to form a protective chromium oxide layer, can be done to protect against any future rust and corrosion [18]. Several sterilization methods (such as steam autoclaving, gamma radiation, hydrogen peroxide plasma, etc.) can be applied to increase biocompatibility, reduce any cytotoxicity effects, and allow for the design to follow clinical-grade standard and be used in a surgical setting [18].

Testing and Results

Thread Tightness Testing

The clamps and detachable jaws are secured to each other by means of threads. The jaws and the clamps have to be screwed together. The threads must be tight to ensure the jaws do not destabilize or detach over the course of the surgery. Blood acts as a natural lubricant and can cause loosening. Viscosity is the most critical characteristic when examining the lubrication abilities of a fluid [19]. A blood analogue fluid with properties similar to those of blood will be used for this testing. The blood analogue fluid (BAF) used will be 40-45% glycerol and 55-60% saline by weight [20]. The BAF will be passed in a container with a velocity of 30cm/s and the jaw-clamp system will be kept in the flow of the fluid. The initial points of the jaw and clamp will be marked before it is kept in the BAF and after a period of time the clamp will be removed from the BAF. For some time while the clamp is in the BAF, the fluid will be stirred to simulate the flow of blood. The amount the jaw loosened will be measured and it will be determined if the amount of loosening will have an effect on the surgery. The ideal result will be that the jaw did not loosen by a significant amount.

Clamping Force Testing

The clamping force of the vascular clamp is one of the most important properties of the instrument. Too much force will cause trauma to the blood vessels and insufficient force will result in the clamping not stopping the flow of blood. The maximum magnitude of force the clamp can generate will be measured using a load cell. The vascular clamp will be clamped to a 2.2mm load cell [21] which will be connected to a system that allows us to read the signal generated due to the clamping. Various systems could be used, one of which is a HX711 board connected to an arduino. A successful result would be wherein the force always stayed in the range of 2 to 5N [22].

Clamp Length Testing

The clamp length is one of the main characteristics of the vascular clamps that must be adjusted for pediatric patients. A clamp of incorrect length can result in various issues such as obstruction of the surgical field, insufficient clamping of blood flow, or physical trauma to blood vessels.

Due to the variation in ages of pediatric patients, it is not possible to state a desirable numerical value or range for the length of the clamp. Thus, the length will be tested by doing the operation in a training laboratory provided by the client. If there are no issues with doing the test, the length will be considered adequate.

Discussion

As testing has not been conducted at this stage of the project, there are no implications of results or anything else to compare to. The only current ethical consideration is making sure that when documents with the patient's wound sizes are received, the knowledge is kept confidential and is used to ensure that the instrument is performing at the required strength and size. The testing must also be performed in the proper manner with the correct training. Due to a lack of testing, there are currently no changes that need to be made. A major source of error is human error due to lack of experience using a load cell or similar equipment while measuring the occlusive force of the clamp.

Conclusions

The most effective treatment plan for most children with end stage renal disease is transplantation surgery [23]. However, this procedure in pediatrics is often harder than transplantation surgery in adults. This design aims to make this procedure easier for surgeons by controlling the amount of force used, to ensure that the smaller pediatric vessels and veins are not damaged because of too much pressure and force on the instrument. The instrument also will feature detachable jaws, which makes it more adaptable to different blood vessel and vein sizes, so it will be easier to use on a wider array of pediatric patients. The force will be controlled using a ratchet system which allows for incremental increases in force and the ability to be locked into a specific position. To release the force, there will be a relief lever that the user can push down on. The jaws will be able to attach and detach using a simple screw-in mechanism. The handles will have threads and the tips will have the matching screws to allow for easy attachment. In the future, we plan to meet with our clients and present to them our final design and fabrication processes, as well as ask them any additional questions that the team has. Then, we will start to create our preliminary prototype in SolidWorks. Once our prototype is complete we will present it to our client and test it based on the criteria above.

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Appendix

Appendix A: Product Design Specification

Function

End-Stage Renal Disease (ESRD) is a condition affecting more than 808,000 people in the United States [1]. Approximately 5,645 of those with the condition are under the age of 18 [2]. Renal transplantation is currently considered the best and most cost-effective treatment for ESRD [3]. A major challenge that arises while performing kidney transplants in children is the lack of appropriate surgical tools and instruments. Current surgical instruments are designed with adult bodies in mind. These instruments are often too large to be used on children's smaller bodies, among other issues. Our clients, Dr. Kelly Collins and Dr. Jennifer Phillips, face this challenge consistently while performing pediatric surgery and asked the team to create a design of a vascular clamp that could be used during kidney transplant surgeries in pediatric patients. The device will be adjusted to more easily access the lesser wound depth corresponding to the body of a pediatric patient while still avoiding a large-sized tool that may obstruct the surgical field. Compared to current designs on the market, the model should also have less clamping strength to prevent any lasting damage to the targeted blood vessels, as pediatric patients often have smaller blood vessels and lower blood pressure [4] than adult patients.

Client requirements

- Instrument should have all features of a standard vascular clamp found in renal transplant surgery, including
 - Appropriately sized and ergonomic finger rings
 - Adult surgical handles should have slightly oval-shaped rings with an internal diameter matching average adult thumb and index finger widths
 - Atraumatic jaws to avoid damage to vessels and any surrounding tissue
 - A strong and maintainable locking mechanism tight enough to stop all blood flow from the objective vessels during anastomosis while preventing any long-lasting crushing or damage to the vessels
 - An overall small enough size to avoid obstruction of surgical field
- The prototype should be adjustable for blocking blood flow in all vessels involved in anastomosis, including
 - An average size adult donor renal artery
 - Typically ranging from 5-6 mm diameter, with an average of 5.6 mm [5]
 - This size range may be subject to change depending on statistical measurements found in the provided CT scan database
 - An average size iliac vein for a recipient of each age group
 - These size ranges will be determined based on statistical measurements found in the provided CT scan database
- Final product should be composed of a safe and biocompatible metal and should be latex-free

- Final product should be autoclavable or able to withstand chemical sterilization with commonly used compounds, and should follow all clinical grade safety standards
- Model should be reusable or produce a framework that is publishable in a research journal and can be adjusted to create a standard medical-grade OR instrument
- Final product should be within the budget of \$200-500

Design requirements

1. Physical and Operational Characteristics

○ Performance requirements

- The clamp shall accommodate the full range of iliac vessel depths measured from pediatric CT imaging of patients aged 0–18 years. The required working depth shall be determined from the imaging dataset.
- The clamp shall maintain a jaw width of approximately 1.6 mm and a jaw length of approximately 58 mm [6], equivalent to the reference adult DeBakey vascular clamp used in kidney transplantation, while reducing the overall instrument depth to accommodate pediatric anatomy.
- The clamp must remain securely positioned on the vessel to avoid any unintended movement or loosening during use.
- The clamp shall generate an adjustable clamping force within the range of approximately 2–5 N [7], sufficient to achieve complete vascular occlusion while minimizing endothelial injury. The final target force will be validated through benchtop testing using simulated pediatric vessels representative of the transplant procedure.
- The clamp must withstand the mechanical loading associated with repeated operation and vessel clamping without permanent deformation or failure.
- The final design shall be compatible with fabrication from surgical-grade, autoclavable metal.

○ Safety

- The final instrument must be made from medical-grade, non-toxic, latex-free materials suitable for use during pediatric kidney transplantation.
- The instrument must provide enough clamping force to temporarily stop blood flow without damaging or excessively compressing the blood vessels.
- The designs should avoid sharp edges, pinch points, or other features that could cause injury to the patient, surgeon, or surgical staff.
- Standard hospital sterilization procedures
- Reusable and durable
- Clinical-grade safety and surgical instrument standards
- Sterile, medical-grade surgical instrument

○ Accuracy and Reliability

- The clamp must consistently reach and engage the target vessel across the expected range of pediatric vessel depths.

- ii. The final design shall be reusable and capable of withstanding repeated steam sterilization cycles (121–134 °C) [8] without loss of mechanical performance or structural integrity. The minimum validated number of reuse cycles will be determined during testing.
 - iii. The prototype shall demonstrate reliable performance in the kidney transplant simulation model across the range of wound depths and vessel diameters representative of the target pediatric population.
- **Life in Service**
 - i. The prototype surgical clamp(s), ideally composed of 3D-printable plastic, should successfully withstand at least one full operation of the kidney transplant simulation model
 - 1. The material must not break down or degrade during the simulated operation
 - 2. The clamp(s) must effectively block the blood flow from the vessels without causing excessive vessel tissue damage
 - ii. The final surgical clamp(s) composed of sterile and medical-grade metal must consistently complete the required function without any material breakdown, corrosion, or failure
 - 1. The model should withstand an estimated 300-900 cycles of sterilization, as is consistent with the lifespan of a typical surgical instrument [9]
 - 2. While a standard kidney transplant surgery can range from 3 to 4 hours, the anastomosis phase at which the vascular clamp is actively applied should span under 40 minutes [10]
 - a. This time limit is in place to avoid any prolonged blood flow restriction or permanent damage to surrounding tissue
 - 3. UW Health Transplant Center reports conducting about 273 to 350 kidney transplant surgeries annually, with about 4% (or 10 to 15 of those surgeries) focusing on pediatric patients [11]
 - 4. As such, the total active operational time for the clamps should range between 200 and 600 hours (to accommodate sterilization restrictions) or 20 to 90 years (to accommodate allowed surgical use)
- **Shelf Life**
 - i. The instrument will most likely be stored in aluminum, double linen wraps, polypropylene, or a sterilization pouch. [9]
 - ii. The instrument may be stored for up to 96 weeks in a room that should ideally be double the assembly and decontamination areas combined. [9]
- **Operating Environment**
 - i. The instrument must be capable of undergoing the process of cleaning, disinfecting, and sterilizing for a surgical instrument. This includes cleaning with water, using an enzymatic transport gel or foam, and being plunged into a bath of detergent for 5 to 20 minutes. [12]
 - ii. The instrument surfaces should be resistant to typical sterilization methods of surgical instruments, which could include dry heat, autoclave for up to one hour,

- or chemicals such as ethylene oxide, hydrogen peroxide, chlorine dioxide, peracetic acid, or aldehydes. [12]
- iii. The instrument must be able to go through approximately 300-900 cycles of sterilization. [9]
- iv. The instrument must be able to function in standard operating room environments, which are recommended to be 20 to 23 degrees Celsius, but can get as low as 17 degrees Celsius or as high as 27 degrees Celsius, and have a humidity from 20%-60%. [12]
- v. The instrument must be able to handle occasional jostling without misaligning.
- **Ergonomics**
 - i. The instrument should be comfortable for the surgeon to use for long periods of time.
 - ii. The instrument should require minimal hand force to open, close, and adjust while still providing sufficient clamping force to securely occlude the vessel.
- **Size**
 - i. The instrument must be appropriately sized for pediatric kidney transplant patients, while still allowing access to an adult-sized donor kidney and vascular structures.
 - ii. The design should account for differences in surgical depth, since depth does not necessarily correlate directly with the patient's age or overall size.
 - iii. The instrument should not simply be scaled down from an adult instrument, as reducing the size may prevent it from reaching or properly accommodating the adult kidney and vascular system.
 - iv. The design should consider multiple sizes or adjustable dimensions to accommodate the wide range of pediatric patient anatomies.
 - v. The instrument must be long enough to reach the necessary surgical structures while remaining compact enough to provide adequate access within the pediatric surgical field.
 - vi. Dimensions should be informed by cross-sectional CT imaging of pediatric kidney transplant patients rather than relying solely on age-based measurements.
- **Weight**
 - i. The instrument should be lightweight enough for comfortable handling and precise manipulation by the surgeon during a delicate kidney transplant procedure.
 - ii. The weight should be minimized without compromising the strength and rigidity required for safe surgical use.
 - iii. The instrument should be appropriate for a metal, reusable surgical instrument, while the initial prototype can be lighter or made from other materials for testing.
 - iv. The weight should be balanced with the required clamping force, ensuring the instrument is strong enough to stop blood flow without unnecessarily increasing its size or weight.
- **Materials:**
 - i. Prototype clamps can be fabricated with 3D-printed plastic materials, which allows the team to make rapid and low-cost alterations.

- ii. Materials like PLA and PETG will be used as long as they provide equivalent or sufficient durability and force.
- iii. Final products will be manufactured from a medical-grade metal by a qualified manufacturing company.
- iv. This final material must be appropriate for surgical use and should provide sufficient strength, durability, and reusability with the sterilization process.
- v. Materials that deform, corrode, or release harmful substances during surgical use or cleaning should not be used for the final product.
- **Aesthetics, Appearance, and Finish:**
 - I. The surgical clamp(s) will have a compact design that allows them to be easily positioned and used in the small abdomen of pediatric patients.
 - II. The jaws should have a smooth and curved shape without any sharp edges or surfaces that could damage the tissue or vessel.
 - III. The final clamp will be medical-grade that is smooth, and polished, allowing for easy cleaning and sterilization.
 - IV. The different clamp sizes will have a consistent design while having different scaled dimensions for various vessel sizes.
 - V. The prototype appearance and surface may vary due to limitations of 3D-printing.

2. Production Characteristics

- **Quantity:**
 - I. The number of prototypes will be determined based on the CT scan analysis and how much the team adjusts the design.
 - II. The scans will provide the information required to identify the number of different-sized clamps needed.
 - III. A design and specification will be made for each size, but to save money on prototypes, a select few sizes will be chosen for testing.
 - IV. The final product quantity will be determined by the manufacturing company based on the required clamp sizes and demand.
- **Target Product Cost:**
 - I. The total cost of designing and prototyping should remain within the \$200-\$500 budget range provided by the client.
 - II. Prototype clamps will be primarily made using 3D-printed plastic to minimize the cost during the design and testing phases.
 - III. The clamps will be constructed from a medical-grade metal by a qualified manufacturing company. Their production cost is expected to be greater than the team's prototypes, and that cost will be covered separately by the hospital.
 - IV. Commercial vascular clamps such as the DeBakey and bulldog-style typically cost between \$150-\$350 or more per piece depending on the manufacturer and design [13].

- V. The final product does not need to be less expensive than the existing clamps; however, the manufacturing cost should be reasonably similar to the other surgical clamping instruments.

3. Miscellaneous

○ Standards and Specifications

- i. While metal, non-powered surgical instruments are usually exempt from the FDA 510(k) premarket notification, this device requires consideration of this standard as it is a novel device with a new design and new intended clientele [14] under the limitations of regulation 21 CFR 878.9.
- ii. This device will be classified as a Class I medical device due to being a manual device with basic and general controls [14] and hence must follow regulations of 21 CFR 878.4800.
- iii. This is a novel medical device and hence must follow the FDA regulation 21 CFR Part 820, which sets good manufacturing practices to ensure good quality.
- iv. The FDA requires that all regulated medical devices be labelled; hence, the device must follow regulation 21 CFR Part 801, which specifies what exact labels the device must have regarding the name and place of business of the manufacturer.
- v. ISO 7153-1:2016 specifies what materials are safe to use for the manufacture of metal surgical instruments, and the device must be made of a metal on the approved list to be permitted for global use.
- vi. ISO 13485 specifies rules for quality management, manufacturing, and lifecycles of medical devices, and the device will need to meet the requirements of this standard to be sold in global markets.
- vii. ISO 7151 is a standard that lays out rules for non-cutting surgical instruments. Since the vascular clamp is a non-cutting tool, this standard must be followed.

○ Customer

- i. This model is necessary for providing a precise and adjustable tool or set of tools intended to efficiently block blood flow in vessels without resulting in long-term damage for the patient.
- ii. The potential customer(s) for this vascular clamp set are pediatric transplant surgeons specializing in the renal and urinary system.
- iii. Aspects that customers would value most include
 1. An atraumatic mechanical grip that is tight enough to prevent any loosening or slippage of the vessel but gentle enough to avoid causing endothelial tearing or structural damage to pediatric arteries and veins.

2. Interchangeable or adjustable jaws of varying sizes to effectively accommodate several vessel diameters found in pediatric patients ranging from infants to adolescents.
 3. An easily maneuverable and lightweight vascular tool that allows for precise clamping without heavily obscuring the encountered surgical field.
 4. Material that can maintain structural durability through a minimum of 300 to 900 high-heat autoclave or chemical sterilization cycles.
- iv. Design features that the clients have expressed dislike for and should be avoided include
1. Excessive force caused by a rigid closure mechanism that poses the risk of crushing vessels and causing surrounding tissue damage or necrosis.
 2. Extreme friction, jaw misalignment or mechanical failure at the hinge of the clamps during progressive use
 3. Material degradation or corrosion after continued life in service.
- **Patient-related concerns**
 - i. This device will be used invasively during surgery and therefore needs to be sterilized between uses.
 - ii. This device has mechanical actuation and has no electrical components or data storage capabilities, due to which there is no risk of patient data leak.
 - **Competition**
 - i. Competing Design #1: Pediatric DeBakey Vascular Clamp[6]
 - The pediatric DeBakey vascular clamp is designed for pediatric vascular surgery and features a reduced overall size while providing atraumatic temporary occlusion of blood vessels during vascular anastomosis. The clamp improves maneuverability in smaller surgical fields compared to standard adult vascular clamps.
 - While the pediatric DeBakey clamp is better suited for pediatric anatomy, scaling down the entire instrument also reduces the jaw dimensions. As a result, it may not adequately accommodate the adult-sized renal vessels encountered during pediatric kidney transplantation.
 - ii. Competing Design #2: Standard Adult Vascular Clamp[7]
 - Standard adult vascular clamps, such as DeBakey and Satinsky clamps, are routinely used during adult kidney transplantation and provide reliable temporary vessel occlusion with jaw dimensions appropriate for adult donor renal vessels.
 - Although these clamps effectively accommodate adult vessels, their overall length and working depth are optimized for adult anatomy, making them difficult to maneuver within the smaller operative field of pediatric kidney transplant recipients.

iii. Competing Design #3: Atraumatic Vascular Clamp Designs [15]

- Existing patented atraumatic vascular clamps incorporate features such as resilient jaw surfaces, optimized jaw geometry, and interchangeable components to improve vessel contact while minimizing tissue injury during temporary vascular occlusion.
- While these designs reduce vessel trauma and improve clamping performance, they do not address the need to modify the overall instrument geometry for pediatric surgical access while maintaining adult-sized jaw dimensions.

iv. Competing Design #4: Enhanced Vessel Grip Vascular Clamps [16]

- Several patented vascular clamp designs improve vessel grip and clamping consistency through modified locking mechanisms, jaw profiles, and force distribution, allowing secure vessel occlusion with reduced risk of slippage.
- Although these designs enhance clamp performance, they are intended for general vascular surgery and do not address the unique challenge of pediatric kidney transplantation, where the instrument must combine a pediatric working depth with compatibility with adult-sized vessels.

Current vascular clamp designs are optimized either for adult vascular surgery or general pediatric vascular procedures. None of the identified devices are specifically designed for pediatric kidney transplantation, where the clamp must preserve adult-sized jaw dimensions while reducing the overall working depth to improve access within the smaller operative field of pediatric recipients. This gap motivates the development of a specialized pediatric transplant vascular clamp, which represents the primary design opportunity for our project.

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Materials and expenses

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Makerspace 3D Printing Costs										
									\$0.00	
									\$0.00	
Other Supporting Purchases										
									\$0.00	
									\$0.00	
								TOTAL:	\$0.00	
								Budget:	Undecided	
								Financial Standing:	GOOD	